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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,420	06/05/2002	Toshihiro Nakajima	50026/031001	2866
21559	7590	10/06/2004	EXAMINER	
CLARK & ELBING LLP			BURKHART, MICHAEL D	
101 FEDERAL STREET			ART UNIT	
BOSTON, MA 02110			PAPER NUMBER	

1636

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,420

Applicant(s)

NAKAJIMA ET AL.

Examiner

Michael D. Burkhardt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/5/02; 3/6/02; 1/20/04; 7/14/04</u> | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Priority

This application, filed 6/5/2002, is a 371 of PCT application JP 00/03955, filed on 6/16/2000. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statements filed 1/20/2004 and 7/14/2004 fail to comply with 37 CFR 1.98(a)(3) because they do not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

The information disclosure statement filed 7/14/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 16, and 17 recite a vector DNA with a "RRE core sequence". Applicants provide no definition of what the RRE "core sequence" comprises, i.e. what portion(s) of the RRE are included in the core sequence? The metes and bounds of the claimed subject matter are unclear. This rejection affects all dependent claims

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Naldini et al. (Science, 1996, cited by applicants). The instant claims recite a DNA vector comprising, in order, from 5' to 3': an expression regulatory sequence; a splice donor sequence; a first foreign gene insertion site; a RRE core sequence; a splice acceptor site; and a second foreign gene insertion site. The RRE and splice sites may be of retro-, lenti-, or immunodeficiency virus

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origin, the regulatory sequence may be an LTR, the vector may contain a packaging signal of retro-, lenti-, or immunodeficiency virus origin and may not express a complete gag protein.

Naldini et al. disclose a vector based on Human Immunodeficiency Virus (HIV) that comprises (5' to 3'), an HIV LTR (expression regulatory sequence), a splice donor site, an insertion (insertion site) of truncated HIV *gag* and *env* sequences containing the RRE followed by a splice acceptor site, and an insertion of either the *lacZ* or *luciferase* reporter genes. The vector also contains the HIV packaging signal and the gag protein is not expressed due to a frameshift mutation and truncation (see entire document, especially Fig. 1).

Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Naldini et al. (U.S. Patent 5,994,136, 1999). The instant claims are as described above, except the expression regulatory sequence may be other than an LTR and may be from the group consisting of the CMV, CMVL, and EF1 α promoters. Naldini et al. disclose a vector based on Human Immunodeficiency Virus (HIV) that comprises (5' to 3'), an HIV LTR (expression regulatory sequence), a splice donor site, an insertion (insertion site) of truncated HIV *gag* and *env* sequences containing the RRE followed by a splice acceptor site, and an insertion of either the *lacZ* or *luciferase* reporter genes. The vector also contains the HIV packaging signal and the gag protein is not expressed due to a frameshift mutation and truncation (see entire document, in particular Figure 1). The expression regulatory sequences may also be the CMV or RSV promoter (Figure 2).

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Conclusion

No claims are allowed.


The closest prior art regarding claims 10-30 are the Naldini et al. references cited above. However, the Naldini references do not teach the exact 5' to 3' sequence of the vector recited in claims 16-30: that is the Naldini gene insertion site is 3' to the splice donor and 5' of the RRE, in contrast to the sequence of components of the vector in claims 16-30. Regarding claims 10-15, Naldini et al. do not specifically teach mutation of the gag initiation codon, nor the insertion of a foreign gene in the first insertion site. Naldini et al. insert a truncated HIV sequence into the first insertion site of an HIV vector, hence it cannot be considered a foreign gene.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart
Examiner
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DAVID G. GUSS
PRIMARY EXAMINER